

September 9, 1998

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical and it is presented here exactly as submitted.

1333 North California Blvd.
Suite 600
P.O. Box 8025
Walnut Creek, CA 94596-8025
(510) 256-2700

ASM

15/OPP #34136



June 11, 1996

**NALED REREGISTRATION:
EXPOSURE CONSIDERATIONS**

Case No.:	0092 Naled
EPA Chemical No.:	034401
EPA Company No.:	59639

Mr. Lawrence J. Schnaubelt
Office of Pesticide Programs
Document Processing Desk, H7504C
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

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Dear Mr. Schnaubelt:

In the interest of advancing the dialogue which may lead to a resolution of EPA concerns over exposure of the insecticide naled to workers and the environment, Valent is offering additional information which may be helpful to EPA. Based on the availability of use reporting data from the State of California, and a demonstration of the fact that the majority of naled's agricultural use occurs in California, it is evident that worker and environmental risk may be less than has been assumed by EPA, and that worker exposure mitigation is already in place by regulation. Based on these same data, Valent is requesting EPA reconsider its assumptions regarding maximum daily acres treated in the calculation of handler margins of exposure. Finally, Valent is requesting latitude in the imposition of deadlines for conduct of dislodgeable foliar residue studies, and in the selection of study design, pending completion of discussions between EPA and the industry Agricultural Reentry Task Force (ARTF).

Naled Usage - Geographical Distribution vs. Worker and Environmental Risk

Because full pesticide use reporting is required by law in California, and because the majority of naled's agricultural use is in California, use of naled in agriculture is extremely well characterized. The California EPA Department of Pesticide Regulation (CDPR) recently released its Annual Pesticide Use Report for 1994¹; data for naled agricultural use is summarized in an attached table. 1994 is the most recent year for which use reporting data are available from California.

¹These data may be directly accessed via the internet at <http://www.cdpr.ca.gov/docs/dprdocs/docsmenu.htm>

In order to determine the proportion of total naled use for agriculture occurring in California, Valent has compared its total sales for DIBROM 8 Emulsive to data contained in the CDPR Annual Pesticide Use Report for 1994. As shown in the attached table, naled uses totalled 877,103 lbs. a.i. during 1994. This figure somewhat exceeds Valent's recorded sales of DIBROM 8 Emulsive for 1994. We know that a limited amount of product is in fact sold outside California, but allowing for differences in the way that Valent and CDPR collect and record sales/use data, CDPR's data confirms our contention that well over 90% of naled agricultural use occurs in California.

Also, many crops on the naled agricultural use label are found exclusively in California, or have limited acreage outside California, as demonstrated in the following table:

	Year	U.S. Acreage ²	CA Acreage ²	% CA / U.S. Acres
Almonds	1994	403,000	403,000	100
Broccoli	1992	111,600	97,000	87
Cauliflower	1992	55,900	42,000	75
Celery	1992	36,220	23,500	65
Grapes	1994	761,430	654,800	86
Melons, Honeydew	1992	27,600	18,000	65
Walnuts	1994	171,000	171,000	100

Furthermore, the EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances, dated June 2, 1994, indicates that 95% of Brussels sprouts are grown in Region X (CA/AZ).

In total, these data suggest that the potential exposure to workers and the environment from agricultural use of naled may be less than previously assumed. For example, for almonds, which represent the highest use rate on the DIBROM 8 Emulsive label (Valent has committed to cap the rate at 2.8 lbs. a.i./acre), the 1994 CDPR use report indicates only 52 applications were made to a total of 1,906 acres. This represents the entire usage of naled on almonds, as no almonds are grown commercially outside California.

Because of the predominant use of naled for agriculture in California, mitigation of worker exposure is already in place by regulation. The California Code of Regulations, Title 3, §6746(a), reads as follows:

²Acreage figures compiled from USDA reports on *Noncitrus Fruits and Nuts (PNF-BB)* and *Vegetables - Final Estimates 1987-92* (National Agricultural Statistics Services Statistical Bulletin Number 902).

"Employers shall provide closed systems for employees that mix or load liquid pesticides in toxicity category one, or load diluted liquid mixes derived from dry pesticides in toxicity category one, for the production of an agricultural commodity. No employee shall be permitted to transfer, mix, or load these pesticides except through a closed system. The system's design and construction shall meet the director's closed system criteria."

The only Valent naled formulation registered for agricultural uses, DIBROM 8 Emulsive (EPA Reg. No. 59639-15) is clearly covered by this regulation.

In its March 8, 1996 review of handler exposure data and arguments submitted by Valent on December 14, 1995, EPA rejected alternate estimates of daily maximum acres treated, for use in margin of exposure calculation. In the attached table (far right column), Valent has calculated the average acres treated per application by crop, using CDPR figures for number of applications and total acres treated. These data confirm the soundness of Valent's original proposals, and underscore the conservatism of EPA's analysis of naled exposure to handlers, especially for the ground boom and aerial application scenarios. Valent appreciates that EPA revised its exposure estimates to reflect application rate, and that the estimate of maximum acres applied was revised from 800 to 350 acres for aerial applications. However, EPA has chosen to retain default acreage assumptions of 80 acres applied per day by ground and 350 acres/data by air, in the face of data which bely these assumptions. Such defaults are appropriate in the case where a high level of uncertainty exists in the information about pesticide usage. *This is not the case with naled.* California's use reporting data show that there are very pronounced crop-specific and rate-specific differences in acreage applied, which are ignored by default assumptions. For example, in the case of crops treated with 1.875 lbs. a.i. per acre by ground, EPA's default assumption exceeds the actual average acreage applied (by ground *and* air) by a factor of 5 to 40.

In conclusion, it is unusual to have as comprehensive and credible a database as CDPR's to describe the use of any pesticide. Valent appeals to EPA to rely on these data to keep the overall risk assessment for naled in perspective. The presented data support Valent's contention that well over 90% of naled's agricultural usage occurs in California, where safeguards for handlers are the strictest in the nation. Valent believes that usage on certain crops with special concern for worker and environmental risk may be less than has been assumed by EPA. Finally, the EPA is working with industry (Acute Cholinesterase Risk Assessment Task Force and Best Management Practices Task Force) on a new paradigm for worker risk assessment and exposure mitigation for cholinesterase-inhibiting chemicals. While Valent is not offering new mitigation for worker exposure at this time, we agree to meet any standards for risk assessment and mitigation that are mutually agreed upon by EPA and industry.

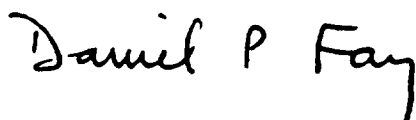
Reentry Data

EPA has required that a certain number of dislodgeable foliar residue studies be conducted to support continuing use of naled, and that certain restricted entry intervals (REI) be established for such crops until such time as the new data are available and reviewed supporting alternate REIs.

Valent is a member of the Agricultural Reentry Task Force (ARTF), which will develop data for chemicals other than naled in response to a generic DCI issued for agricultural reentry exposure data. The ARTF is currently working with EPA on development of generic guidance regarding conduct of dislodgeable foliar residue studies, including number of sites required, the number of different crop types to be tested, and certain other details of study design. Valent is concerned that a reregistration data call-in may be issued for naled without the benefit of such guidance. Therefore, Valent respectfully requests that any requirement for additional dislodgeable foliar residue data be subject to a final decision by EPA regarding acceptable study design for ARTF studies, and that an extension be granted for the conduct of naled studies, until such a decision is reached.

If you have any questions, please call me at (510) 256-2770, or Brent Solomon at our Washington, D.C. office (202) 872-4682.

Sincerely,



Daniel P. Fay
Project Manager
Registration & Regulatory Affairs

Attachments

cc: Robert Forrest/OPP/RD/PM Team 14
Susan Jennings/OPP/SRRD

④

1994 California Naled Agricultural Usage (excerpted from California Environmental Protection Agency, Department of Pesticide Regulation, *1994 Annual Pesticide Use Report Indexed by Chemical*)

Crop	No. Applications	Lbs. A.I. Applied	Acres Treated	Acres per Application
Almonds	52	4482	1906	37
Beans	112	4286	5075	45
Broccoli	805	16923	11460	14
Brussels Sprouts	175	4374	3048	17
Cabbage	342	3295	2285	7
Cabbage, Chinese	4	44	32	8
Cauliflower	343	6827	4499	13
Celery	512	7074	6086	12
Collards	47	145	93	2
Cotton	3520	746722	333670	95
Eggplant	1	0.3	1.5	1.5
Grapefruit	5	45	48	9
Grapes (incl. wine)	1,041	21374	23109	22
Kale	422	3395	2024	5
Lemon	10	61	66	7
Orange	663	19017	16788	25
Peach	2	70	74	37
Peas	89	453	1049	12
Peppers	2	23	25	13
Rangeland	5	127	134	27
Safflower	83	18424	26022	314
Strawberry	601	8495	9327	16
Sugarbeet	97	7639	8177	84
Swiss chard	235	316	222	1
Tangerine	18	165	143	8
Walnut	88	3327	3158	36
TOTAL		877103		